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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,817	09/17/2003	Harry A. Dugger III	3633-038-999	4051
7590	03/25/2004		EXAMINER	
PENNIE & EDMONDS LLP 1667 K Street, N.W. Washington, DC 20006				HAGHIGHATIAN, MINA
		ART UNIT		PAPER NUMBER
		1616		

DATE MAILED: 03/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/663,817	DUGGER, HARRY A.
	<b>Examiner</b>	<b>Art Unit</b>
	Mina Haghigian	1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 14-22 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 14-22 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 17 September 2003 is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 09/17/03
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Kanios et al (5,719,197).

Kanios teaches compositions and methods for topical administration of pharmaceutically active agents. Topical administration means a direct contact of the formulation with tissue, such as skin or membrane, particularly the oral or buccal mucosa (col. 1, lines 29-59).

Kanios discloses that the composition comprises a therapeutically effective amount of at least one pharmaceutically active agent, a pharmaceutically acceptable solvent for the active agent (col. 2, lines 22-28). The solvent is preferably a polyhydric alcohol such as polypropylene glycol, ethylene glycol, also solvents including fatty acids such as oleic acid, as well as fatty esters or alcohols. The solvent is present in an amount from about 20 to 50 weight percent based on the total weight of the composition (col. 4, lines 1-49; col. 5, lines 24-66). The concentration of the solubilized active agent can range from 1 to 50% by weight (col. 8, lines 1-9). The acceptable carrier is intended to be any suitable finite or non-finite carrier including liquids, semi-liquids or solid carriers. Thus the active agent may be admixed with carriers such as spray-solution or

any non-finite carrier known in the art for delivery of active agents (col. 8, lines 54-67). Other additives may be incorporated into the formulations such as flavorings (col. 10, lines 48-56).

Kanios discloses that pharmaceutically active agents suitable for such formulation include variety of active agents such as antibiotics, antivirals, antiemetics, prostaglandins, etc (columns 13-31).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15-16 and 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kanios et al (5,719,197) in view of Singer et al (5,364,616).

Kanios, discussed above, lacks specific disclosure on the concentration range and examples of the flavoring agents and aqueous polyethylene glycol and aqueous ethanol.

Singer teaches methods for prevention or treatment of gingivitis or periodontitis comprising topical administration to oral cavity, a composition comprising a safe and effective amount of a selective histamine-2 receptor antagonist compound, and oral care compositions used thereof. Compositions comprise about 0.001 to about 20% of a

H-2 antagonist such as cimetidine, about 2 to about 99% of an oral carrier and about 0.04 to about 2% of flavoring agent by weight. The suitable carriers include ethanol, water and polyhydric alcohols such as glycerin, polyethylene glycol and propylene glycol. Suitable flavoring agents include menthol, oil of wintergreen, oil of peppermint, oil of clove, etc (col. 15-17).

Singer discloses that the said compositions, suitably in the form of a mouthspray, may optionally include other agents such as other active agents such as antibiotics, anti-inflammatories, vitamins and minerals (col. 18-19).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made, given the general teachings on the topical (oral) spray formulations of Kanios to look in the art for relative and suitable concentration range and examples of the flavoring agent, as taught by Singer et al, with the reasonable expectations of preparing an oral formulation that is acceptable and tolerable by patients, since flavoring is an important aspect of oral formulations. One of ordinary skill is also motivated to, given the various possible solvents to have looked in the art for other suitable solvents, including combinations such as water and ethanol to improve solubility and stability of compositions.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11

F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 20 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 6,676,931. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 20 is generic to all that is recited in claims 1 and 2 of U.S. Patent No. 6,676,931. That is, claims 1 and 2 of U.S. Patent No. 6,676,931 falls entirely within the scope of claim 20 or, in other words, claim 20 is anticipated by claims 1 and 2 of U.S. Patent No. 6,676,931.

Specifically, claim 20 of the instant application recites a propellant free spray composition containing an active compound in the amount of 0.005 to 55 % by weight and a polar solvent in an amount between 37 and 98.58 % by weight of the total composition. The active agent is selected from a group of active agents including cyclosporin and ondansetron. Claim 1 of U.S. Patent No. 6,676,931 recite the same propellant free spray composition containing cyclosporin. Claim 2 of U.S. Patent No. 6,676,931 recite the same propellant free spray composition containing ondansetron hydrochloride.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghightian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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